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Technology
& Engineering

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June 10, 2008

US EPA Office of Pollution Prevention and Toxics
EPA East Building Room 6428
Attn: Section 8(e)
1201 Constitution Avenue, NW
Washington, DC 20004

8EHQ-07-16907

SUBJECT: TSCA 8(e) Notice

8908000223

Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals, LLC, we are submitting results of an OECD 422 study conducted with ethaneperoxoic acid, 1,1-dimethylethyl ester (CAS #107-71-1) 50% solution in aliphatic hydrocarbon solvent (CAS # 64742-48-9). A summary of findings from the range-finding study were previously submitted (8EHQ-07-16907).

The test material was prepared as a suspension in water with 1% carboxymethyl cellulose which was also used as the vehicle control. Dose groups were: vehicle control, 50, 150, and 500 mg/kg. Doses were administered daily by oral gavage.

Three males in the high dose group died due to pronounced ulceration of the fore stomach. All other animals survived until scheduled necropsy. Clinical signs of toxicity in the high dose group included ruffled fur, irregular breathing, ventral recumbency, uncoordinated gait and cold to touch. In addition, animals in the mid and high dose group were observed moving their heads through bedding material following administration. Food consumption was reduced in the high dose female group during pre-pairing and gestation while there was a dose-related decrease in food consumption in all male groups. Mean body weights were decreased in a dose-related manner in both males and females.

In the functional observational battery (behavioral investigation) slight piloerection, reduced activity, reduced rectal body temperature and slightly reduced locomotor activity were observed in some of the animals in the high dose group.

Clinical chemistry revealed an increase in total leukocyte count, absolute and relative neutrophils and platelets indicating an inflammatory response in males of the high dose group.

There was a statistically significant increase in absolute and relative liver weight in males and females of the high dose group. The absolute and relative weights of adrenal glands and spleen were statistically significantly increased in females in the high dose group. The relative weight of these same organs was increased in the males of this group.

Macroscopic examination of the high dose group, revealed abnormalities which were considered adaptive such as thickened mucosa of the fore stomach (4/10 males), dilated duodenum (7/10 males), altered mesenteric lymph nodes (3/10 males), fibrin-like coatings in the spleen (3/10 females), thickened mucosa of the duodenum and jejunum (2/10 females), or adherences in the abdominal cavity (1/10 female). The thymus in males (5/10) in this group was reduced in size.

Histopathology in the high dose group revealed changes in the stomach, small intestine, adrenal cortices, thymus, liver, bone marrow, spleen, mesenteric lymph nodes, and Peyer's patches and in the

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reproductive organs of males. Changes in the stomach of the majority of animals included acanthosis, parakeratosis, ulcerations, hemorrhage in one male, and inflammation. Mucosal hyperplasia was noted in the duodenum, jejunum and ileum of males. These changes are indicative of the severe irritant property of the test article. Changes in the lymphatic system included atrophy of the thymus in males (8/10) and in the Peyer's patches of males (6/10) and females (3/10). Lymphoid depletion was present in the spleen white pulp and in the mesenteric lymph nodes (3/10 males and 1/10 females). Increased extramedullary hematopoiesis in the spleen (6/10 males, 3/10 females) and increased cellularity in the bone marrow were present in both males (3/10) and females (5/10). Hemosiderin deposits and congestion were observed in the spleen of males (5/10) and females (2/10). There was a high incidence of congestion in mesenteric lymph nodes in males (4/10) and in 1/10 females. Centrilobular hypertrophy of the hepatocytes was observed in both males (7/10) and females (5/10). One male exhibited liver necrosis. Hemopoiesis was noted in the liver of one male and one female. Diffuse hypertrophy of the adrenal cortex and vacuolation were noted in males (2/10) and females (4/10). The changes in the cortex were considered secondary to stress.

The stomachs of animals in the mid and low dose group were affected as were sections of the small intestine but to a lesser degree of severity. Hemopoiesis in the spleen was also noted in the control (1/10), low (2/10), and mid-dose (2/10) groups as well but also to a lesser degree.

Reproductive organ affects were noted in males of the high dose group and included tubular atrophy of the seminiferous tubules associated to germ cell depletion (2/10) and spermatic giant cells (2/10) and in one animal to Sertoli cell vacuolation. In one of these animals the tubular atrophy was minimal and unilateral. In the two animals affected by germ cell depletion, all types of the germ cells were affected and only the Sertoli cells were still present in the tubules. In the epididymides of the same animals, cellular debris was present and consisted of residual bodies of germinal cells whereas atrophy was observed in one animal. However the changes were mild in nature and focal or multifocal. The mild effect was also confirmed by the absence of a reduction of the testicular and epididymal weights. Usually testicular and epididymal weights are affected if there are relevant reproductive toxic effects, particularly over a treatment period of 28 days. There was also no effect on the tubular stages. Atrophy of the prostrate, seminal vesicles and coagulating glands were also noted in a few animals (3/10). In two of the animals there was a correlation between these changes and those in the testes.

In the high dose group there was a decrease in the implantation rate, a statistically significantly increase in post-natal loss, with the viability index decreased and smaller litter weight and slightly smaller pup weight.

The No Observed Adverse Level for reproductive and developmental effects was 150 mg/kg/day and for parental effects based on GI tract findings, 50 mg/kg/day.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.

Sincerely,

Louette Rausch

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